K073153

510(K) Summary
As Required by 21 CFR 807.92

510(k) Number: _____

FEB 26 2008

1. Submitter Information

Submitter Name:	GE Medical Systems SCS 283, rue de la Minière 78533 Buc Cedex, FRANCE
Establishment Reg:	9611343
Contact Person:	Stephen Slavens Global RA Premarket Director 3000 N Grandview Blvd. Waukesha, WI 53188 Tel: 262-548-4992 Fax: 262-548-4710 stephen.slavens@ge.com
Date Prepared:	August 22nd, 2007

2. Device information

Trade Name:	CardIQ Function Xpress
Common Name:	Picture Archiving and Communication Device
Classification Name:	System, Image Processing, Radiological
Procode:	JAK
Class:	Class II per 21 CFR 892.1750

3. Predicate Devices

CardIQ Function Xpress is substantially equivalent to the predicate devices listed below:

Device Name	FDA Clearance
GE CardIQ Analysis III	K041267
GE CardIQ Function	K013422

4. Device Description

The GE Medical Systems **CardIQ Function Xpress** software is a post processing software option for the Advantage Workstation (AW) Platform, CT scanner, PACS or Centricity systems. This product can be used in the analysis of CT angiographic images to calculate and display ventricular analysis of several functional cardiac parameters. The software has the ability to select the chambers of the heart and diastolic and/or systolic phases to determine the hearts function. **CardIQ Function Xpress** contains both graphic and text report capabilities with predefined templates for ease of use.

5. Indication for Use

CardIQ Function Xpress is intended to provide an optimized non-invasive application to analyze cardiovascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

CardIQ Function Xpress in conjunction with CT cardiac images to automatically calculate and display various left ventricular and right ventricular functional parameters as ejection fraction, end systolic and end diastolic volumes, stroke volumes, wall motion, wall thickening, cardiac output, myocardial mass, systemic and pulmonary vascular resistance. Volume measurement of each chamber of the heart is also available. With **CardIQ Function Xpress** atrium volumes may be used to determine volume assessment of atrial disease to include but not limited to atrial fibrillation. **CardIQ Function Xpress** is a CT, non-invasive image analysis software package, which aids in the assessment of cardiac function and in determination of cardiovascular disease diagnosis and management.

CardIQ Function Xpress is for use on the Advantage Workstation (AW) platform, CT Scanner, PAC or Centricity stations, which can be used in the analysis of 2D or 3D CT angiography images/data derived from DICOM 3.0 CT scans.

6. Summary of non-clinical and/or clinical tests and results

The software was designed to meet the following standards:

Standard	Standards Organization	Standard Title
PS 3.1 - 3.18	NEMA	Digital Imaging and Communications in Medicine (DICOM)
SW68	AAMI/ANSI	Medical Device Software - Software life cycle processes

Software and medical device design validation have been completed. Medical device design included testing and evaluation of previously acquired diagnostic images.

The results concluded the device was acceptable for use.

7. Statement of Equivalence

The General Electric CardIQ Function Xpress workstation software is equivalent to a combination of the predicate General Electric CardIQ Analysis III and CardIQ Function devices and is safe and effective for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

FEB 26 2008

GE Medical Systems SCS
% Mr. Jay Y. Kogoma
Senior Staff Engineer – Medical Devices
Intertek Testing Services
2307 E. Aurora Road, Unit B7
TWINSBURG OH 44087

Re: K073153
Trade/Device Name: CardIQ Function Xpress
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, LLZ
Dated: February 8, 2008
Received: February 11, 2008

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073153

Device Name: CardIQ Function Xpress

Indications For Use: **CardIQ Function Xpress** is intended to provide an optimized non-invasive application to analyze cardiovascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073153